

## REMARKS

Reconsideration of the rejections set forth in the Office action mailed September 16, 2003 is respectfully requested.

### I. Amendments

Applicants have presented a new set of claims in an endeavor to simplify the layout of the claim set, and to clearly distinguish the features of the invention from the pertinent 102(b) references, as discussed further below.

The new claims correspond closely to previously presented claims, as follows:

- Claim 40 corresponds to previous claim 1 as it was presented in the response filed April 9, 2002, with the inclusion of language ("non-native" and "the same as, overlapping...") added by amendment in that response.

Newly added to this independent claim is the language:

--wherein said DNA binding compound, when bound to said binding sequence, is effective to modulate binding of said transcriptional regulatory protein to said DNA response element.--

Support for this language is found, for example, at page 15, lines 42-43 and page 31, lines 1-4 of the specification.

- Claim 41 is a new dependent claim. Support for claim 41 is found, for example, in original method claim 18, as well as page 27, lines 7-9.
- Claim 42 corresponds to original claim 2.
- Claim 43 corresponds to original claim 7.
- Claim 44 corresponds to original claim 8.
- Claim 45 corresponds to original claim 11.
- Claim 46 corresponds to original claim 12.
- Claim 47 corresponds to original claim 14.
- Claim 48 corresponds to original claim 13.
- Claim 49 corresponds to original claim 15.
- Claim 50 corresponds to original claim 16.
- Claim 51 corresponds to original claim 17.

- Independent claim 52 corresponds to claim 18 as presented in the response filed April 9, 2002, with the inclusion of language ("non-native" and "the same as, overlapping...") added by amendment in that response.
- Claim 53 corresponds to original claim 19.
- Claims 54-59 correspond to original claim 21-26.

No new matter is added by any of the amendments.

## II. Objections to the Claims

Claim 12 was objected to because it appeared to recite an element twice. In view of the cancellation of claim 12, this objection is obviated.

Applicants note that claims 45 and 46, which essentially replace claims 12 and 13, have been drafted with this objection in mind.

## III. Rejections under 35 U.S.C. §112, Second Paragraph

Claim 6 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, because the claim appeared to recite that a "first nucleic acid construct" included a "second nucleic acid construct" and a "DNA binding compound".

In view of the cancellation of claim 6, this objection is obviated.

Applicants note that independent claim 40 has been drafted with this objection in mind, so that the elements of the respective nucleic acid constructs are clear and consistent, and do not include the DNA binding compound.

In view of the foregoing, the applicants submit that the pending claims comply with the requirements of 35 U.S.C. §112, second paragraph.

## IV. Rejections under 35 U.S.C. §102(b)

Claims 6, 12, 21-26 and 34-39 were rejected under 35 U.S.C. §102(b) as being anticipated by Bujard *et al.* (WO 94/29442).

In view of the cancellation of these claims, the rejection is addressed with respect to independent claim 40. (Applicants note that the only other independent claim presented

herein, claim 52, is identical to previous claim 18, which was found free of the prior art.)

Because independent claim 40 recites subject matter similar to previous claim 1 as presented with the response of April 9, 2002, the applicants also address the 102(b) reference cited in the subsequent Office Action of March 27, 2003, i.e., Goldstein *et al.* (U.S. Patent No. 5,527,690).

In describing the disclosure of Bujard *et al.*, the Examiner states that "The tTA acts not only as a transcriptional regulatory protein but also as a DNA binding compound" (page 4 of current Office Action).

In the Office Action of March 27, 2003, in describing the disclosure of Goldstein *et al.*, the Examiner stated, similarly, that "SREBP-1 acts not only as a transcriptional regulatory protein but also as a DNA binding compound" (page 3 of 3/27/03 Office Action).

The Examiner's arguments appear to hinge on the assertion that the previous claims encompass a system in which the "transcriptional regulatory protein" and the "DNA binding compound" are the same entity.

In response, the applicants have presented an independent claim (claim 40) which recites that "said DNA binding compound, when bound to said binding sequence, is effective to modulate binding of said transcriptional regulatory protein to said DNA response element." This language could not logically include a system in which the "transcriptional regulatory protein" and the "DNA binding compound" are the same entity (as shown in the cited references), since a compound could not logically "modulate binding of" itself.

Dependent claim 41 further recites that, in one embodiment, "said DNA binding compound, when bound to said binding sequence, is effective to *inhibit* binding of said transcriptional regulatory protein to said DNA response element." Clearly, a compound would never "*inhibit* binding of" itself.

In view of the foregoing, the applicants respectfully request the Examiner to withdraw the rejections under 35 U.S.C. §102(b).

V. Conclusion

In view of the foregoing, the applicant submits that the claims now pending are now in condition for allowance. A Notice of Allowance is, therefore, respectfully requested.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4403.

Respectfully submitted,



LeeAnn Gorthey  
Registration No. 37,337

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**Correspondence Address:**  
PAYOR NUMBER 22918  
PHONE: (650) 838-4403  
FAX: (650) 838-4350